

REMARKS/ARGUMENTS

Upon entry of the instant reply, claims 30-63 will remain pending. Claims 30, 44, 55 and 61-63 are independent claims.

Reconsideration and withdrawal of the rejections of record are respectfully requested.

Overview Of Office Action And Discussion Of Brief Telephone Discussion With Examiner

Applicants express appreciation for the vacating of the August 31, 2004 Office Action and the reduction of issues in the present Office Action.

Moreover, Applicants note that prior to issuing the present Office Action, the Examiner contacted the undersigned to briefly indicate that issues were being reduced, and indicating that an Office Action may be mailed wherein an obviousness-type double patenting rejection over Bedford, U.S. Patent No. 5,624,678, would be made. Arguments were briefly presented by Applicants' representative that such a rejection would not be appropriate when it appears that this patent qualifies as 102(b) prior art. In particular, it was noted that the patent issued April 29, 1997 which is more than one year prior to the July 16, 1998 effective filing date of the present application, based upon the filing of PCT/EP98/04440 on July 16, 1998.

The Examiner appeared to desire the filing of a Terminal Disclaimer over Bedford '678 despite the fact that the document qualifies as prior art under 102(b). The Examiner

was asked to reconsider this position, and Applicants would await receipt of further communication from the Patent and Trademark Office.

Still further, Applicants note that the European counterpart of the Bedford patent, i.e., EP 0681787 A2, published November 11, 1995, and has been considered by the examiner. In this regard, the examiner has initialed consideration of the European counterpart on the Form PTO-1449 attached to the Office Action mailed August 15, 2000.

Restriction Requirement

Applicants note that the each of the pending claims has been examined on the merits in the present Office Action. Therefore, Applicants express appreciation for the withdrawal of the Restriction Requirement with an action on the merits of each of the pending claims.

Rejections

The Office Action sets forth two rejections over Bedford, as follows:

(1) Claims 30-63 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No.5,624,678 to Bedford.

(2) Claims 30-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No.5,624,678 to Bedford.

In response to these grounds of rejection, Applicants respectfully submit that the rejections are without appropriate basis, and should be withdrawn.

Initially, Applicants respectfully submit that the Office Action does not set forth any basis for the rejections. The rejections merely allege that it would have been obvious to treat a chicken having a bacterial infection with xylanase based upon Bedford's disclosure of a method of treating an animal for coccidiosis with a xylanase. The rejection does not indicate how Bedford is being modified or where there is any motivation in the prior art for modifying Bedford to arrive at Applicants' claims.

The examiner is reminded that, as set forth in MPEP 2143, in order to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Also, the prior art reference must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in Applicants' disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

A rejection cannot merely make an assertion of obviousness without setting forth what modifications are being made and where the motivation is for making the modification. Moreover, as noted above, there must be a reasonable expectation of success.

Thus, for at least the reason that the rejections do not comply with the requirement for establishing a *prima facie* case of obviousness set by the case law and Patent and Trademark Office practice, the rejections should be withdrawn.

Moreover, it is readily apparent that Bedford does not support a *prima facie* case of obviousness. Bedford is directed to methods and compositions for treatment and/or prophylaxis of coccidiosis in an animal comprising administering to the animal an agent comprising a therapeutically effective amount of a carbohydrase, such as xylanase, as a therapeutically active agent for treatment and/or prophylaxis of coccidiosis. Therefore, Bedford does disclose a method of treating an animal suffering from coccidiosis by administering a xylanase. However, coccidiosis is fundamentally unrelated to the bacterial infections caused by *Salmonella*, *Campylobacter* or *Clostridium perfringens*. The examiner is reminded that Applicants' claims are directed to methods which involve bacterial infection caused by bacteria selected from the group consisting of *Salmonella*, *Campylobacter*, *Clostridium perfringens*, and mixtures thereof.

To assist the Examiner's understanding of differences between the treatment of coccidiosis, which is an infection caused by protozoa, *Eimeria*, and bacterial infections caused by *Salmonella*, *Campylobacter* or *Clostridium perfringens*, Applicants submit herewith extracts from the book "Diseases of Poultry- 10th Edition", edited by B.W.

Calnek, Mosby-Wolfe, published in 1997 by Iowa State University Press, pp. v-vii, 81, 97-111, 236-242, 261-263, 865-883.¹

As can be seen from a review of the contents pages v-vii, protozoas are dealt with entirely separately in Chapter 34 compared to the bacterial infections of *Salmonella*, *Campylobacter* and *Clostridium* which are dealt with in Chapters 3, 10 and 12 respectively. *Salmonella*, *Campylobacter* and *Clostridium* are all classical bacteria. *Eimeria* is a protozoa which is not a bacteria. Simply because xylanase may be used to treat a disease caused by a protozoa provides no motivation for treatment of bacterial diseases in the manner disclosed and claimed by Applicants. In this respect, the examiner should bear in mind that even bacterial infections caused by different bacteria are often treated by different medicaments.

Coccidiosis is generally treated by administering so-called coccidiostats. A list of these is provided in Bedford, at column 3, lines 48-52, wherein it is disclosed that a conventional non-enzymic anticoccidial agent such as salinomycin, monensin, narasin, lasalocid, nicarbazin, maduramycin, nicarbazin and narasin in combination, diclazuril, dinitolmide, halofuginone, robenidine, amprolium or clopidol can be used.

Applicants further note that Chapter 34 in the enclosed extract of Diseases of Poultry teaches various regimes for treating coccidiosis on its pages 874- 876. The use

¹ The document is being submitted in accordance with MPEP 609(C)(3) as part of Applicants' reply to the Office Action in support of an argument so that the requirements of 37 C.F.R. 1.97 and 1.98 need not be met, and the information is being submitted as part of the record with the reply for the Examiner's consideration with Applicants' reply.

of vaccines is further mentioned on page 878. Such compounds have a specific mode of action as described on page 875 and would generally not be considered useful for treating classical bacterial infections.

Regarding typical prior art treatments for *Salmonella*, *Campylobacter* and *Clostridium perfringens*, for example, *Salmonella* vaccination is typically carried out in young poultry (pullets) before egg laying commences in order to reduce the incidence of *Salmonella* contamination in eggs. Generally *Salmonella* and *Campylobacter* do not have any negative effect on the birds themselves in terms of performance and mortality. The real issue though is that *Salmonella* and *Campylobacter* are a significant problem for humans in the case that food, such as meat or eggs, are contaminated with these zoonotic organisms because they can cause extremely unpleasant enteric diseases in humans. Other precautions that are taken to reduce or prevent *Salmonella* contamination include high temperature treatment of feed (to reduce feed contamination), poultry house disinfection, carcass washing within-the slaughterhouse, and a recommendation on thoroughly cooking eggs and meat before consumption.

Turning to *Campylobacter*, so far there has not been developed a focused strategy for dealing with this but the industry is moving towards protocols that are similar to those which are used to treat *Salmonella*. Vaccination is not used though because the chickens do not live sufficiently long enough to develop an immune response to the vaccine.

Applicants respectfully submit that one having ordinary skill in the art would not be motivated to apply the disclosure of Bedford directed to the treatment for coccidiosis

against bacterial infections let alone Applicants' recited bacterial infections caused by *Salmonella*, *Campylobacter* or *Clostridium perfringens*.

In view of the above, it is readily apparent that neither of the obviousness rejections are appropriate. Thus, the claims of the present application are not obvious over the claims of Bedford. Moreover, the disclosure of Bedford does not render Applicants' claims obvious. Therefore, the rejections of record should be withdrawn.

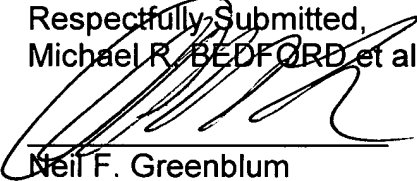
CONCLUSION

For the reasons advanced above, Applicants respectfully submit that all pending claims patentably define Applicants' invention.

Allowance of the application with an early mailing date of the Notices of Allowance and Allowability is therefore respectfully requested.

Should the Examiner have any further comments or questions, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully Submitted,
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